UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

Civil Action No.
1:11-cv-00017

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TAMMY GILBERT, individually and as administrator,
of the Estate of Kira Nicole Gilbert
Hamilton County, Ohio
Probate Court Case No. 2010005566

Judge

and

COMPLAINT FOR WRONGFUL DEATH AND OTHER RELIEF

JOHN GILBERT

Plaintiffs,

-against-

XANODYNE PHARMACEUTICALS, INC.

and

ELI LILLY AND COMPANY,

and

DOES, 1-99
Jane and John Doe(s), individual(s),
corporation(s) limited liability company(ies),
and business entity(ies)
Names and addresses unknown

Defendants.

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Now come Plaintiffs, Tammy Gilbert, on behalf of herself individually and as the duly appointed and acting administrator of her deceased daughter, Kira Nicole Gilbert [hereinafter, "Tammy Gilbert"] and John Gilbert [hereinafter, collectively, "Plaintiffs"], upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceed $75,000.00, exclusive of interest and costs, and because Defendants, XANODYNE PHARMACEUTICALS, INC. and ELI LILLY AND COMPANY are incorporated and have their respective principal places of business in states other than the state in which the named Plaintiffs reside.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Southern District of Ohio.

NATURE OF THE CASE

4. This action is brought on by Tammy Gilbert on behalf of her deceased daughter, Kira Gilbert [hereinafter, "decedent"], who was prescribed, purchased and correctly used DARVOCET, also known generically as Propoxyphene Napsylate and Acetaminophen.

5. Defendants, XANODYNE PHARMACEUTICALS, INC. and ELI LILLY AND COMPANY (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed DARVOCET for use as a prescription pain management medication.

6. Defendants concealed their knowledge of DARVOCET's defects, from decedent, the FDA, the public in general and/or the medical community specifically.

7. When warning of safety and risks of DARVOCET, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to decedent and the public in general, that DARVOCET had been tested and was found to be safe and/or effective for its indicated use.

8. These representations were made by Defendants with the intent of defrauding and deceiving decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase DARVOCET for use as a prescription pain management medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning DARVOCET's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, during clinical trials, forcing decedent, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other prescription pain management medications, which does not entirely and/or necessarily apply to DARVOCET whatsoever.

10. As a result of the defective nature of DARVOCET, those persons who use and/or used and relied on DARVOCET have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Decedent herein died as a result of in addition to certain other of the above health consequences all due to her use of DARVOCET prior to her untimely passing at twenty-two (22) years of age.

12. Defendants concealed its knowledge of the defects in its product from the decedent, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiffs seek compensatory damages as a result of decedent's use of DARVOCET, which has caused decedent's death and other injuries prior to her death and has caused Plaintiffs' loss of consortium of their daughter, Kira Gilbert, including diminished enjoyment of life and loss of her companionship, among other losses.

PARTIES PLAINTIFF

14. Plaintiff, TAMMY GILBERT, is a natural person and is a resident of the State of Ohio, and she is, and was, the natural and biological mother of the decedent, and is the duly appointed administrator of her Estate in Hamilton County Probate Court Case Number 2010005566, as set forth in the Entry Appointing Fiduciary attached hereto as Exhibit A.

15. Plaintiff, JOHN GILBERT, is a natural person and is a resident of the State of Ohio and he is, and was, the natural and biological father of the decedent, and along with TAMMY GILBERT, are the next of kin of the decedent pursuant to Ohio's statutory intestate succession laws.

16. Prior to her death on April 9, 2009, decedent did not have a pre existing cardiac history.

17. Decedent was prescribed DARVOCET for pain management on or about April 1, 2009 related to her knee surgery and ingested DARVOCET consistent with the prescription until her passing on April 9, 2009.

18. As result of using Defendants' drug DARVOCET, decedent was caused to suffer acute cardiac failure with evidence of pulmonary edema, among other injuries, leading to her death on April 9, 2009.

19. Decedent used DARVOCET in the manner in which it was prescribed to her in the days and hours prior to her acute cardiac failure with evidence of pulmonary edema and other injuries that caused her death on or about April 9, 2009.

20. Decedent was caused to sustain severe injuries, pain, suffering, emotional distress, and premature death all related to her use of DARVOCET.

PARTY DEFENDANTS

21. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., and at all relevant times was and is a corporation organized under the laws of the State of Delaware, with its principal place of business located in the State of Kentucky.

22. Upon information and belief, at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., has transacted and conducted business in and throughout the State of Ohio and derived substantial revenue from interstate commerce.

23. Upon information and belief Defendant XANODYNE PHARMACEUTICALS, INC., expected or should have expected that its acts would have consequences within the United States of America, and Cincinnati, Ohio and within the confines of the Southern District of Ohio in particular and derived substantial revenue from interstate commerce.

24. Upon information and belief, and at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription

management medication

25. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., is the holder of approved New Drug Application for DARVOCET.

26. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., is the holder of approved New Drug Application for Darvocet.

27. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., obtained the rights to the approved New Drug Application for Darvocet from AAIPHARMA SERVICES in or around May 2005.

28. Upon information and belief, AAIPHARMA SERVICES, obtained the rights to the approved New Drug Application for Darvocet from Defendant ELI LILLY AND COMPANY in or around February 2002.

29. Upon information and belief, Defendant ELI LILLY AND COMPANY, and at all relevant times was, a corporation organized under the laws of the State of Indiana, with its principal place of business located in the State of Indiana.

30. Upon information and belief, at all relevant times Defendant ELI LILLY AND COMPANY, has transacted and conducted business in the State of Ohio and derived substantial revenue from interstate commerce.

31. Upon information and belief Defendant ELI LILLY AND COMPANY, expected or should have expected that its acts would have consequences within the United States of America, and Cincinnati, Ohio and within the confines of the Southern District of Ohio in particular and derived substantial revenue from interstate commerce.

32. Upon information and belief, and at all relevant times Defendant ELI LILLY AND COMPANY, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Darvocet for use as a prescription management medication.

33. Upon information and belief, Defendant ELI LILLY AND COMPANY, was the original holder of the approved New Drug Application for Darvocet.

34. Upon information and belief, and at all relevant times Defendant, ELI LILLY AND COMPANY, licensed, amongst other things, its "know-how" and "trademarks to commercialize Darvon and Darvocet and any other pharmaceutical product containing the active pharmaceutical ingredient Propoxyphene in the United States" to XANODYNE PHARMACEUTICALS, INC.

FACTUAL BACKGROUND

35. Upon information and belief, Defendant ELI LILLY AND COMPANY was the original holder of the approved NDA application for Darvocet over 50 years ago and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendant who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Darvocet for use as a prescription pain management medication for over 40 years.

36. Upon information and belief, Defendant ELI LILLY AND COMPANY continues to benefit from the sale of Darvocet and does so because has continued to license its "know-how" and "trademarks to commercialize Darvon and Darvocet and any other pharmaceutical product containing the active pharmaceutical ingredient Propoxyphene in the United States" to Defendant XANODYNE PHARMACEUTICALS, INC

37. Upon information and belief AAIPHARMA SERVICES, obtained the rights to the approved New Drug Application for Darvocet from Defendant ELI LILLY AND COMPANY in or around February 2002.

38. Upon information and belief, Defendant XANODYNE PHARMACEUTICALS, INC., obtained the rights to the approved New Drug Application for Darvocet from AAIPHARMA SERVICES in or around May 2005

39. At all relevant times, Defendants were and remain in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or acquired the a Defendant who designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed DARVOCET for use as a prescription pain management medication.

40. At all times relevant, defendant, XANODYNE PHARMACEUTICALS, INC., focused its sales on pain management products including DARVOCET because the area of pain management offers attractive commercial opportunities in significant markets in the United States; see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

41. At all times relevant, defendant, XANODYNE PHARMACEUTICALS, INC., affirmatively decided not to take part in full discovery research of its products because defendant believed that it was more beneficial for it to advance products quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market, see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

42. By using a strategy of moving its products through the research and development process expeditiously defendant, XANODYNE PHARMACEUTICALS, INC., believes it can reach its goal of becoming a leading integrated specialty pharmaceutical

company that develops and commercializes new products for significant markets in pain management, http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

43. About 10 million people in the U.S. received prescriptions for DARVOCET and Propoxyphene related drugs, in 2009 according to the FDA.

44. Upon information and belief, Adverse Event data maintained by the FDA indicates staggering, serious Adverse Events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

45. Defendants ignored the correlation between the use of DARVOCET and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

46. In June 2009, the European Medicines Agency (EMEA) recommended that the marketing authorizations for Propoxyphene be withdrawn across the European Union for safety concerns.

47. Despite being petitioned by public interest groups to investigate whether DARVOCET was linked to serious and potentially fatal heart arrhythmias, Defendants refused to do so until July 2009, when it was ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of DARVOCET on the heart.

48. Decedent experienced a fatal myocardial infarction (heart attack) on April 9, 2009 as a result of taking DARVOCET.

49. The results of the study order by the FDA indicated that even when taken at recommended doses, Propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), can increase the risk

for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

50. On November 19, 2010, the FDA announced that defendant, Xanodyne Pharmaceuticals, Inc., had agreed to halt all U.S. Marketing of DARVOCET after it was determined that the drugs benefits were outweighed by the risks associated with its use, specifically the potential of the drug to cause serious and potentially fatal heart arrhythmias.

51. The use of DARVOCET creates unique and dangerous risks compared to other prescription pain management medications. These risks include, including inter alia heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

52. The Defendants did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been repeated by the medical community.

53. By reason of the foregoing, decedent suffered myocardial infarction (heart attack) that caused her death as well as other severe and personal injuries prior to her death and her next of kin, the Plaintiffs' herein, suffered the loss of consortium of their twenty-two year old daughter and the consequent loss of enjoyment of life and severe mental anguish and psychological trauma.

FEDERAL REQUIREMENTS

54. Defendants had an obligation to comply with the law in the manufacture, design, and sale of DARVOCET.

55. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

56. With respect to the prescription drug DARVOCET, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for DARVOCET and such deviations are not plainly stated on their labels.

c. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug DARVOCET does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug DARVOCET is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of DARVOCET cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug DARVOCET.

l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug DARVOCET are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

m. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug DARVOCET and other drugs in the same pharmacologically active and chemically related class.

p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug DARVOCET.

q. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug DARVOCET violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug DARVOCET violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug DARVOCET violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug DARVOCET violates 21 CFR § 211.165 in that the prescription drug DARVOCET fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug DARVOCET violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug DARVOCET were not followed.

w. The prescription drug DARVOCET violates 21 CFR § 310.303 in that the prescription drug DARVOCET is not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug DARVOCET as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug DARVOCET, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug DARVOCET or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendant violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

57. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants negligent *per se*.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURING

58. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

59. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of DARVOCET.

60. The DARVOCET manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury.

61. As a direct and proximate result of Plaintiffs' use of DARVOCET as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing, and Plaintiffs suffered harm, damages, and the loss of consortium of their daughter.

62. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80 and Ohio's wrongful death statute, as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—DEFECTIVE MANUFACTURING--
PURSUANT TO OHIO REVISED CODE SECTION 2307.74

63. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

64. Plaintiff, Tammy Gilbert and decedent are "claimants" as defined at Ohio Rev. Code §§ 2307.71(A)(1)(b)(1) and (2), respectively, in that they are making a "product liability claim," as defined by Ohio Rev. Code §§ 2307.72(A)(13) for damages caused by their use of DARVOCET, an "ethical drug" as defined by R.C. 2307.71(A)(4), manufactured, designed, sold, distributed, supplied and/or placed this product in the stream of commerce by Defendants who are "manufacturers" as defined by Ohio Rev. Code §§ 2307.71(A)(9) and/or "suppliers" as defined by Ohio Rev. Code §§ 2307.71(A)(15).

65. The DARVOCET manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product

specifications, posing a serious risk of injury, regardless of whether Defendants exercised all possible care in its manufacture or construction.

66. The foregoing acts and/or omissions of Defendants were in violation of Ohio Rev. Code §2307.74 since the DARVOCET manufactured by Defendants was defective in manufacture or construction.

67. As a direct and proximate result of Plaintiffs' use of DARVOCET as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

68. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A) and Ohio's wrongful death statute, as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT

69. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

70. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of DARVOCET.

71. The DARVOCET manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

72. The foreseeable risks associated with the design or formulation of DARVOCET, include, but are not limited to, the fact that the design or formulation of DARVOCET is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

73. As a direct and proximate result of decedent's use of DARVOCET as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

74. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DESIGN DEFECT PURSUANT TO OHIO REVISED CODE SECTION 2307.75

75. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

76. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of DARVOCET.

77. The DARVOCET manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with its design or formulation, as defined by Ohio Rev. Code §§ 2307.75(C), or it was more dangerous than an ordinary consumer would expect.

78. As set forth in the Factual Background of this Complaint, at paragraphs 35 through 53 and violations of Federal Requirements, the foreseeable risks of DARVOCET, as defined at Ohio Rev. Code §§ 2307.75(B)(1) – (5), include but are not limited to the following:

(a) the unreasonable risk of the product causing serious adverse events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death, among other unreasonable risks, as defined at Ohio Rev. Code §§ 2307.75(B)(1);

(b) the unlikely awareness to the users of DARVOCET of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of DARVOCET, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);

(c) the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use for pain management, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);

(d) the design or formulation of the DARVOCET produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, safer methods of pain management medication, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(4);

(e) the design or formulation of the DARVOCET produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using DARVOCET for pain management, among other reasons, all as defined at Ohio Rev. Code §§ 2307.75(B)(5)

79. The Defendants failed to provide an adequate warning as to the risks of DARVOCET and for this reason Defendants may not claim that DARVOCET is not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

80. As a direct and proximate result of Plaintiffs' use of DARVOCET as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

81. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A), as well as Ohio's wrongful death statute, as set forth below.

82. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive

damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

FIFTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY – DEFECT DUE TO INADEQUATE WARNING

83. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

84. The DARVOCET manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

85. The DARVOCET manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of DARVOCET, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

86. As a direct and proximate result of decedent's use of DARVOCET as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

87. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80 as well as Ohio's wrongful death statute, as set forth below. Further,

Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—DEFECTIVE DUE TO INADEQUATE WARNING--PURSUANT TO OHIO REVISED CODE SECTION 2307.76

88. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

89. The DARVOCET® manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

90. In addition to, or in the alternative, the DARVOCET manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of DARVOCET, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

91. The risks of DARVOCET were not open and obvious, as defined at Ohio Rev. Code §§ 2307.76(B).

92. Upon information and belief, the warnings provided to physicians who dispense DARVOCET, including the physician(s) that prescribed DARVOCET to decedent, were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

93. As a direct and proximate result of Plaintiffs' use of DARVOCET as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

94. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A) as well as Ohio's wrongful death statute, as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

SEVENTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY DUE TO NON CONFORMANCE WITH REPRESENTATIONS

95. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

96. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of DARVOCET and made representations regarding the character or quality of DARVOCET.

97. The DARVOCET manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

98. Decedent justifiably relied upon Defendants' representations regarding DARVOCET when she used DARVOCET.

99. As a direct and proximate result of decedent's use of DARVOCET and her reliance on Defendants' representations regarding the character and quality of DARVOCET, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

100. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80 as well as Ohio's wrongful death statute, as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION
STRICT PRODUCTS LIABILTY DUE TO NON CONFORMANCE WITH REPRESENTATIONS PURSUANT TO R.C. 2307.77

101. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

102. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of DARVOCET and made representations regarding the character or quality of DARVOCET.

103. The DARVOCET manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

104. Decedent justifiably relied upon Defendants' representations regarding DARVOCET when she used DARVOCET.

105. Upon information and belief, the warnings provided to physicians who dispense DARVOCET, including the physician(s) that prescribed DARVOCET to decedent, were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

106. As a direct and proximate result of Plaintiffs' use of DARVOCET as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

107. As a direct and proximate result of the foregoing, Plaintiffs are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A) as well as Ohio's wrongful death statute. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

NINTH CAUSE OF ACTION
NEGLIGENCE

108. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

109. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of DARVOCET into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

110. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of DARVOCET into interstate commerce in that Defendants knew or should have known that using DARVOCET created a high risk of unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

111. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not DARVOCET was safe for use; in that Defendants herein knew or should have known that DARVOCET was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling DARVOCET without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of DARVOCET;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, DARVOCET;

(g) Failing to test DARVOCET and/or failing to adequately, sufficiently and properly test DARVOCET.

(h) Negligently advertising and recommending the use of DARVOCET without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that DARVOCET was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that DARVOCET had equivalent safety and efficacy as other prescription pain management medications;

(k) Negligently designing DARVOCET in a manner which was dangerous to its users;

(l) Negligently manufacturing DARVOCET in a manner which was dangerous to its users;

(m) Negligently producing DARVOCET in a manner which was dangerous to its users;

(n) Negligently assembling DARVOCET in a manner which was dangerous to its users;

(o) Concealing information concerning FDA warnings from the Plaintiff in knowing that DARVOCET was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of DARVOCET compared to other prescription pain management medications.

112. Defendants under-reported, underestimated and downplayed the serious dangers of DARVOCET.

113. Defendants negligently compared the safety risk and/or dangers of DARVOCET with other prescription pain management medications.

114. Defendants was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of DARVOCET in that it:

(a) Failed to use due care in designing and manufacturing DARVOCET so as to avoid the aforementioned risks to individuals when DARVOCET was used for prescription pain management;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of DARVOCET;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of DARVOCET;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning DARVOCET;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(b) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of DARVOCET;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of DARVOCET, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

115. Despite the fact that Defendants knew or should have known that DARVOCET caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell DARVOCET to consumers, including the decedent.

116. Defendants knew or should have known that consumers such as the decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

117. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

118. As a result of the foregoing acts and omissions, the decedent died at the age of twenty-two years from myocardial infarction (heart attack) and suffered other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

TENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

119. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

120. Defendants expressly warranted that DARVOCET was safe and well accepted by users.

121. The prescription pain management medication DARVOCET does not conform to these express representations because DARVOCET is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

122. Decedent did rely on the express warranties of the Defendants herein.

123. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of DARVOCET as prescription pain medication in recommending, prescribing, and/or dispensing DARVOCET.

124. The Defendants herein breached the aforesaid express warranties, as its drug DARVOCET was defective.

125. Defendants expressly represented to decedent, her physicians, healthcare providers, and/or the FDA that DARVOCET was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other prescription pain management medications, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

126. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that DARVOCET was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

127. As a result of the foregoing acts and/or omissions the decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

ELEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

128. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

129. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET, for use as a prescription pain management medication.

130. At the time Defendants marketed, sold, and distributed DARVOCET for use by Plaintiff, Defendants knew of the use for which DARVOCET was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

131. The Defendants impliedly represented and warranted to the users of DARVOCET and their physicians, healthcare providers, and/or the FDA that DARVOCET was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

132. That said representations and warranties aforementioned were false, misleading, and inaccurate in that DARVOCET was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

133. Decedent, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

134. Decedent and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether DARVOCET was of merchantable quality and safe and fit for its intended use.

135. The prescription pain management medication DARVOCET was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the product and accompanying materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

136. The Defendants herein breached the aforesaid implied warranties, as its drug DARVOCET was not fit for its intended purposes and uses.

137. As a result of the foregoing acts and omissions, decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter

TWELFTH CAUSE OF ACTION
(NEGLIGENT AND FRAUDULENT MISREPRESENTATION)

138. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

139. The Defendants negligently falsely and/or fraudulently represented to the medical and healthcare community, and to the decedent, and/or the FDA, and the public in general, that said product, DARVOCET, had been tested and was found to be safe and/or effective for prescription pain management and/or negligently and fraudulent concealed such facts.

140. The representations made by Defendants were, in fact, false and include, but are not necessarily limited to the following:

(a) that DARVOCET was as safe as other forms of pain management;

(b) that the risks of adverse events with DARVOCET were not higher than those with other prescription pain management medications;

(c) that the risks of adverse events with DARVOCET were adequately tested and/or known by Defendants;

(d) that Defendants were not aware of dangers in DARVOCET, in addition to and above and beyond those associated with other prescription pain management medications;

(e) that DARVOCET was not defective, and that it did not cause dangerous side effects, including but not limited to higher incidence of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, in a much more and significant rate than other prescription pain management medications;

(f) that patients did not need to be monitored more regularly than normal while using DARVOCET;

(g) that DARVOCET was not designed and/or manufactured negligently;

(h) that DARVOCET was not designed and/or manufactured defectively;

(i) that DARVOCET was designed and/or manufactured properly;

141. When said representations were made by Defendants, they knew or should have known those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

142. These representations were made by Defendants with the intent and/or had the consequence of defrauding and deceiving the decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, DARVOCET, for use as a means of prescription pain

management, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the decedent and the Plaintiffs herein.

143. At the time the aforesaid representations were made by the Defendants and, at the time the decedent used DARVOCET, the decedent was unaware of the falsity of said representations and reasonably believed them to be true.

144. In reliance upon said representations, the decedent was induced to and did use DARVOCET, thereby sustaining severe and permanent personal injuries, and being at an increased risk of sustaining severe and permanent personal injuries, and being at an increased risk of premature death.

145. Defendants knew and were aware or should have been aware that DARVOCET had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

146. Defendants knew or should have known that DARVOCET had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

147. Defendants brought DARVOCET to the market, and acted fraudulently, wantonly and maliciously to the detriment of the decedent and the Plaintiffs.

148. As a result of the foregoing acts and omissions, the decedent suffered an untimely death and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

THIRTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT

149. Plaintiffs incorporate by reference each and every paragraph of this

Complaint as if fully set forth herein and further alleges as follows:

150. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and ingestion of DARVOCET by decedent.

151. Defendants have voluntarily accepted and retained those profits and benefits, derived from decedent and/or Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, decedent was not receiving products of the quality, nature, or fitness that had been represented by Defendants, or that the decedent, as a reasonable consumer, expected to receive.

152. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the decedent and/or Plaintiffs, who are entitled in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

FOURTEENTH CAUSE OF ACTION
FALSE ADVERTISING

153. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

154. Defendants knowingly misrepresented DARVOCET as a safe and effective oral contraceptive and knowingly made false statements and omissions of material fact concerning the properties, ingredients, characteristics, qualities, benefits, uses, efficacy, safety, and/or testing of DARVOCET to the decedent, the Plaintiffs and the general public.

155. In its labeling, marketing, direct-to-consumer advertising, promotion, sale, and distribution of DARVOCET, Defendants made untrue, deceptive, and/or misleading material

assertions, representations, and/or statements downplaying risks associated with DARVOCET and exaggerating the drug's safety to the decedent and the general public when Defendants had actual knowledge of the serious, adverse health effects associated DARVOCET including, but not limited to, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

156. Defendants intended to increase the sale and consumption of DARVOCET by falsely marketing DARVOCET as safe and effective, and by concealing facts regarding the dangerous properties of DARVOCET, to thereby induce decedent's physicians to prescribe DARVOCET and to ultimately cause decedent to purchase and consume DARVOCET.

157. In purchasing and consuming DARVOCET, decedent reasonably relied upon Defendants' false and misleading assertions and omissions of material fact that DARVOCET was safe and effective as a pain management medication.

158. As a direct and proximate result of Defendants' false statements as herein alleged, decedent ingested DARVOCET which led to her untimely death caused by myocardial infarction and other injuries prior to her passing and Plaintiffs suffered harm, damages and the loss of consortium of their daughter.

FIFTEENTH CAUSE OF ACTION
WRONGFUL DEATH

159. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

160. Plaintiff, Tammy Gilbert is the duly appointed and acting administrator of the estate of her deceased daughter, Kira Gilbert, born on April 30, 1986. The decedent died in Cincinnati, Hamilton County, Ohio, on April 9, 2009 at the approximate age of twenty-two years. Plaintiff, Tammy Gilbert, states that she was duly appointed the Administrator of the

Estate of Kira Gilbert, deceased, by the Hamilton County Probate Court in Case Number 2010005566, and brings this survivorship and wrongful death action on behalf of the decedent and for the exclusive benefit of the next of kin of decedent. A true and accurate copy of the entry appointing Plaintiff as fiduciary of decedent's estate as set forth herein is incorporated herein and attached hereto as Exhibit A.

161. As set forth herein, decedent ingested DARVOCET and suffered myocardial infarction (heart attack) and other injuries caused by the ingestion of DARVOCET leading to her death on April 9, 2009 at the age of twenty-two years.

162. As a result of the death of decedent, her mother and administrator, Tammy Gilbert, who is a beneficiary pursuant to the laws of intestate succession, suffered damages for loss of decedent, Kira Gilbert's society over his life expectancy, including but not limited to, consortium, companionship, care, assistance, protection, advise, guidance, counseling, instruction, training, and education. She also lost her prospective inheritance.

163. As a result of the death of decedent, her father John Gilbert, who is a beneficiary pursuant to the laws of intestate succession, suffered damages for loss of decedent, Kira Gilbert's society over his life expectancy, including but not limited to, consortium, companionship, care, assistance, protection, advise, guidance, counseling, instruction, training, and education. He also lost her prospective inheritance.

164. As a further result of decedent, Kira Gilbert's untimely death, his beneficiaries suffered, and will continue to suffer indefinitely, profound and extreme mental and physical anguish.

165. As a further result of the death of decedent, Kira Gilbert's, reasonable funeral expenses were incurred, together with other miscellaneous expenses related to her death.

SIXTEENTH CAUSE OF ACTION
SURVIVORSHIP ACTION

166. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

167. As a direct and proximate result of the Defendants' wrongful actions and sale of DARVOCET, a defective drug, decedent suffered profound pain and suffering until the time of her death.

168. As a further result of the care and treatment until the time of her death, decedent incurred medical bills.

169. As a result of the death of decedent, her beneficiaries have suffered and will continue to suffer indefinitely, profound and serious damages and mental and physical anguish.

170. As a direct and proximate result of the wrongful acts and omissions of Defendants herein, decedent was denied all opportunity for effective treatment and care of his condition; suffered mental anguish, emotional distress, and loss of enjoyment of life; incurred substantial, reasonable and necessary medical and other expenses; and lost income.

FITHTEENTH CAUSE OF ACTION
PUNITIVE DAMAGES

171. Plaintiffs hereby incorporate by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

172. At all times material hereto, the Defendant knew or should have known that DARVOCET were inherently more dangerous with respect to the risks of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death than other pain management medication.

173. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety and efficacy of DARVOCET.

174. Defendants' misrepresentation included intentionally withholding material information from the medical community and the public, including decedent, regarding the safety of DARVOCET.

175. Notwithstanding the foregoing, Defendants continued to aggressively market DARVOCET to consumers, including decedent, without disclosing the aforesaid side effects when there were safer alternative forms of pain management medication.

176. The Defendant knew of DARVOCET's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the health and safety of the public, including Plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by DARVOCET.

177. Defendants fraudulently, intentionally, and/or recklessly concealed and failed to disclose to the public, including decedent, the potentially life threatening side effects of DARVOCET in order to ensure continued and increased sales.

178. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of the necessary information to enable the Plaintiffs to weigh the true risk of using DARVOCET against its benefits.

179. The aforesaid conduct of Defendants in the license, approval process, design, manufacturing, assembly, packaging, warning, marketing, advertising, promotion, distribution and sale of DARVOCET was fraudulent, knowing misconduct, willful and/or conduct undertaken to recklessly and with conscious disregard for the safety of decedent such as to

constitute despicable conduct, and oppression, fraud and malice, and at all time relevant, such conduct was ratified by the corporate Defendants herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish and set an example to Defendants, and to deter them from similar conduct in the future.

180. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein pursuant to all appropriate state statutes and common law. The injuries and damages alleged herein are permanent and will continue into the future.

PRESERVATION CLAIM

181. Plaintiffs hereby incorporate by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

182. Many States have recently enacted tort reform statutes with “exclusive remedy” provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or supercede, to any extent, state common law claims. If during the pendency of this action this court makes any such determination, Plaintiffs hereby specifically makes claim to and preserves any State claim found as the result of application of any exclusive remedy provision, to the extent not already alleged above.

DOE DEFENDANTS

168. Does 1-99, inclusive, were and are, but not limited to, individual(s), corporation(s), limited liability company(ies) , business entity(ies) and/or manufacturers of DARVOCET listed in this action, or in some way engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug DARVOCET, which proximately caused or

substantially contributed to decedent's death and Plaintiffs' injuries, whose names, identity and or location could not be identified despite the reasonable diligence of Plaintiffs.

WHEREFORE, Plaintiffs pray for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiffs for all their injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent health conditions, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

6. Such further relief as this Court deems necessary, just, and proper.

7. Punitive damages in excess of twice the compensatory damages and as this court may find appropriate under existing law.

Respectfully submitted,

/s/ Richard W. Schulte
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JURY DEMAND

Plaintiffs demand a trial by jury of all claims asserted in this Complaint.